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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,372	08/15/2003	Dusan Pavcnik	PA-5213-CIP2	2552

9896 7590 02/26/2008

COOK GROUP PATENT OFFICE
P.O. BOX 2269
BLOOMINGTON, IN 47402

EXAMINER	
BLANCO, JAVIER G	
ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
02/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,372	PAVCNIK ET AL.	
	Examiner	Art Unit	
	JAVIER G. BLANCO	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/20/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-28 and 30-39* is/are pending in the application.

4a) Of the above claim(s) *1-7,12-15,19,23-26,30-35 and 37-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,11,16-18,20-22,27,28 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 8, 11, 20, 27, and 36 in the reply filed on November 20, 2007 is acknowledged.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **(i)** claims 1-33 of U.S. Patent No. 6,200,336, **(ii)** claims 1-21 of U.S. Patent No. 6,508,833, and **(iii)** 1-12 of U.S. Patent No. 6,974,474. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 of the application and **(i)** claims 1-33 of U.S. Patent No. 6,200,336, **(ii)** claims 1-21 of U.S. Patent No. 6,508,833, and **(iii)** 1-12 of U.S. Patent No. 6,974,474 lies in the fact that the patent claims include many more elements and is thus much more specific. Thus the invention of **(i)** claims 1-33 of U.S. Patent No. 6,200,336, **(ii)** claims 1-21 of U.S. Patent No. 6,508,833, and **(iii)** 1-12 of U.S. Patent No. 6,974,474 is in effect a "species" of the "generic" invention of claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 8-11, 16-18, 20-22, 27-29, and 36 are anticipated by **(i)** claims 1-33 of U.S. Patent No. 6,200,336, **(ii)** claims 1-21 of U.S. Patent No. 6,508,833, and **(iii)** 1-12 of U.S. Patent No. 6,974,474, it is not patentably distinct from **(i)** claims 1-33 of U.S. Patent No. 6,200,336, **(ii)** claims 1-21 of U.S. Patent No. 6,508,833, and **(iii)** 1-12 of U.S. Patent No. 6,974,474.

4. Claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over:

(i) Claims 1-16 and 55-65 of copending Application No. 09/777,091;

(ii) Claims 1, 7, and 14-25 of copending Application No. 10/721,582;

(iii) Claims 1-19 and 22-42 of copending Application No. 10/910,490;

(iv) Claims 1-20 of copending Application No. 11/185,272; and

(v) Claims 1-29 of copending Application No. 10/828,716.

Although the conflicting claims are not identical, they are not patentably distinct from each other because these applications claim a valve prosthesis comprising leaflets and a support frame/stent enclosed in (and supporting) said leaflets. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Thorpe et al. (US 2003/0130726 A1).

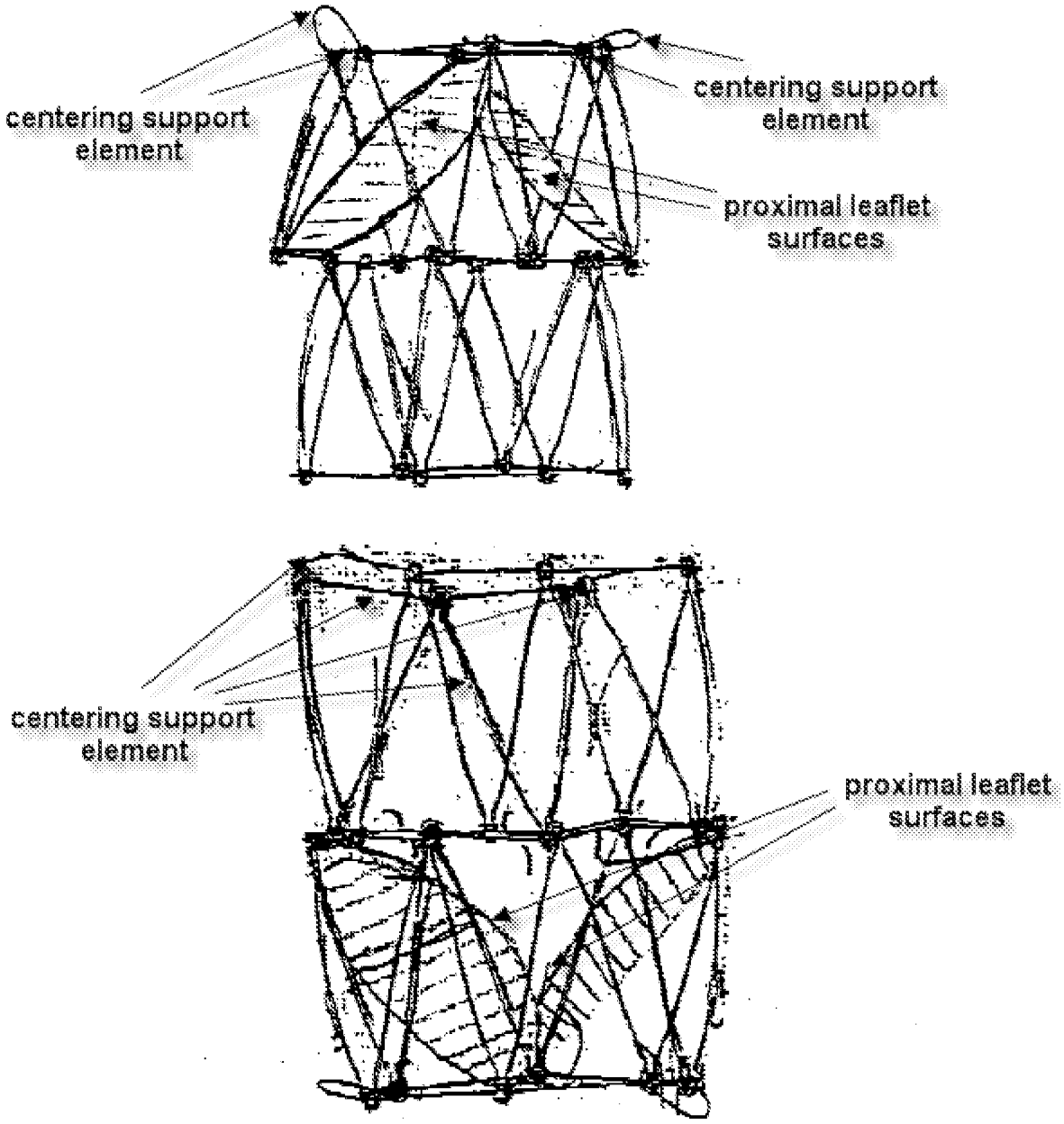
Referring to Figures 9, 11, and 14-16 (particularly Figures 14-16), Thorpe et al. discloses a valve prosthesis (e.g., devices 133, 167) comprising:

(i) A support frame (Figures 14-16: upper stent and/or lower stent) supporting (directly or indirectly) one or more leaflets (e.g., valve material 146), the one or more leaftlets including a co-aptation position (i.e., the one or more leaflets co-apt when their inner edges seal, close, fit together, or contact one another in order to close the valve orifice/opening), wherein the support

frame and one or more leaflet form a valve that restrict blood flow in a first direction and allow blood flow in a second, opposite direction when the valve prosthesis is implanted in a vascular vessel, wherein the valve material comprises one of several materials, including remodelable SIS or extracellular collagen matrix (see paragraph 0037);

(ii) The support frame comprising frame elements/struts (e.g., straight sections 137, 174 AND/OR eye-loops (bends) connecting the straight sections AND/OR marginal retaining members 140, 181) to which the one or more leaflets are attached, wherein outer edges of the frame elements contact/engage the wall of the vascular vessel, at least a portion of the support frame supporting (directly or indirectly) the leaflets of the valve member at a point adjacent (i.e., "lying near, close, or contiguous; nearby") the valve opening (e.g., inner edge 153); and

(iii) At least one centering support element (**first interpretation:** Figures 14-16, lower stent; **second interpretation:** Figures 14-16, any of the straight sections of the upper stent; **third interpretation:** Figures 14-16, marginal retaining members 140, 181) *configured to center* (emphasis added to the functional language) the co-aptation position. As seen in Figures 14-16 (see representation of Figure 16, below), any of the above-indicated interpretations for the "at least one centering support element" includes a portion that traverses and is free of contact with a proximal leaflet surface of one of the two or more leaflets. Further, the claim language does not disclose the orientation of the valve, so "proximal" and "distal" orientations are broadly interpreted and interchangeable.



Response to Arguments

7. Regarding the 102(e) rejection based on Thorpe et al. (US 2003/0130726 A1), Applicants' arguments filed November 20, 2007 have been fully considered but they are not persuasive.

The Applicants argue that Thorpe et al. '601 do not disclose the "centering support element as "including a portion that traverses and is free of contact with the proximal leaflet surface of one of the two or more leaflets". The Examiner respectfully disagrees. As seen in Figures 14-16 (see representation of Figure 16, above), any of the above-indicated interpretations for the "at least one centering support element" includes a portion that traverses and is free of contact with a proximal leaflet surface of one of the two or more leaflets. Further, the claim language does not disclose the orientation of the valve, so "proximal" and "distal" orientations are broadly interpreted and interchangeable.

8. Claims 8, 9, 11, 16, 18, 20-22, 27, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Duerig et al. (US 2002/0138135 A1).

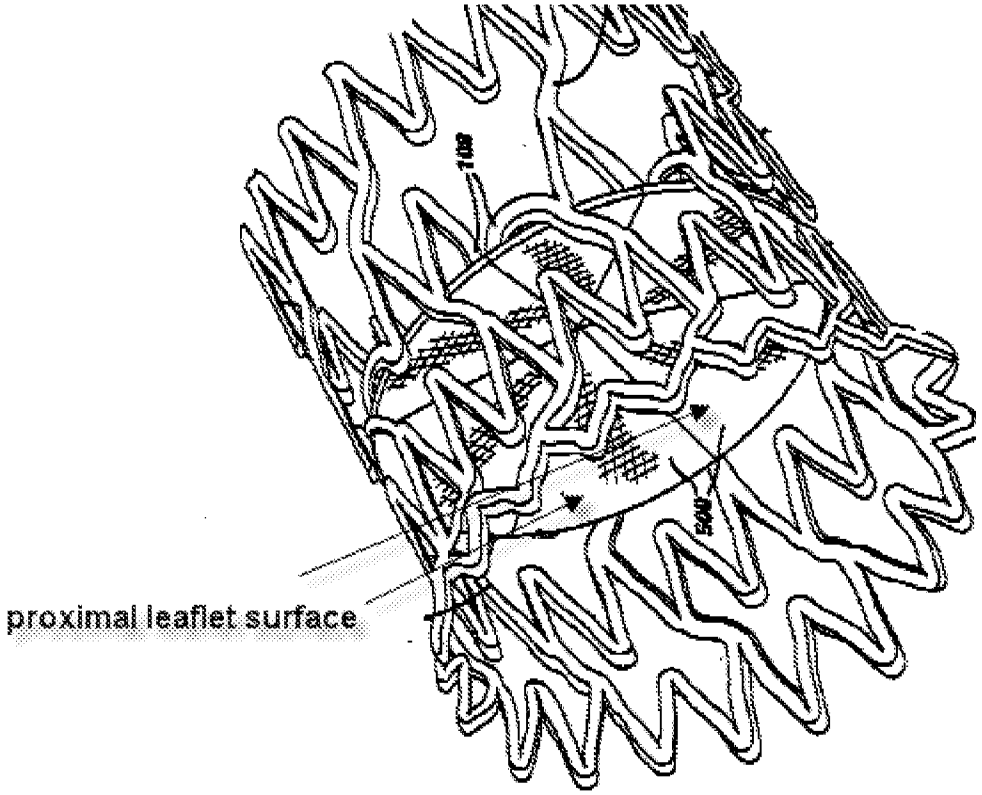
Referring to Figures 5-8, Duerig et al. discloses a valve prosthesis (e.g., devices 500, 600, 800) comprising:

(i) A support frame (**first interpretation:** stent 100; **second interpretation:** bent struts 108, combined) supporting (directly or indirectly) one or more leaflets (e.g., valve flaps 500, 602, 802), the one or more leaftlets including a co-aptation position (i.e., the one or more leaflets co-apt when their inner edges seal, close, fit together, or contact one another in order to close the valve orifice/opening), wherein the support frame and one or more leaflet form a valve that restrict blood flow in a first direction and allow blood flow in a second, opposite direction when the valve prosthesis is implanted in a vascular vessel;

(ii) The support frame comprising frame elements/struts (**first interpretation:** straight struts/segments of stent 100; **second interpretation:** bent struts 108) to which the one or more

leaflets are attached, wherein outer edges of the frame elements contact/engage the wall of the vascular vessel, at least a portion of the support frame supporting (directly or indirectly) the leaflets of the valve member at a point adjacent (i.e., "lying near, close, or contiguous; nearby") the valve opening; and

(iii) At least one centering support element (**first interpretation:** bent struts 108, combined; **second interpretation:** stent 100) extending laterally from the support frame and *configured to center* (emphasis added to the functional language) the co-aptation position. As seen in Figures 6-8, and under the "first interpretation", bent struts 108 include a portion that traverses and is free of contact with a proximal leaflet surface of one of the two or more leaflets. Further, under the "second interpretation", stent 100 include a portion that traverses and is free of contact with a proximal leaflet surface of one of the two or more leaflets. Additionally, the claim language does not disclose the orientation of the valve, so "proximal" and "distal" orientations are broadly interpreted and interchangeable (see representation of Figure 5, below).



Response to Arguments

9. Regarding the 102(e) rejection based on Duerig et al. (US 2002/0138135 A1), Applicants' arguments filed November 20, 2007 have been fully considered but they are not persuasive.

The Applicants argue that Duerig et al. (US 2002/0138135 A1) do not disclose the "centering support element as "including a portion that traverses and is free of contact with the proximal leaflet surface of one of the two or more leaflets". The Examiner respectfully disagrees. As seen in Figures 6-8, and under the "first interpretation", bent struts 108 include a portion that traverses and is free of contact with a proximal leaflet surface of one of the two or more leaflets. Further, under the "second interpretation", stent 100 include a portion that traverses and is free of

contact with a proximal leaflet surface of one of the two or more leaflets. Additionally, the claim language does not disclose the orientation of the valve, so "proximal" and "distal" orientations are broadly interpreted and interchangeable (see representation of Figure 5, above).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (US 2002/0138135 A1) in view of Cox (US 5,713,950 A).

Duerig et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa (an Extracellular Collagen Matrix). However, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Duerig et al., in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

Conclusion

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. This application contains claims 1-7, 12-15, 19, 23-26, 30-35, and 37-39 drawn to an invention nonelected with traverse in the reply filed on March 10, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to

the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738